PATENT
Docket No: 151P9958US02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:

Keith E. Jasperson — Group Art Unit: 3767

Serial No.: 10/809,157

Filed: March 25, 2004 — Examiner: Andrew M. Gilbert

For: METHOD OF DELIVERING A FLUID MEDICATION TO A PATIENT IN FLEX MODE

BRIEF ON APPEAL

Board of Patent Appeals and Interferences
Commissioner for Patents
Washington, DC 20231

This is an appeal from the Office Action mailed on November 7, 2007 finally rejecting claims 1 – 13 of the above-identified application. A Notice of Appeal was timely filed electronically on April 2, 2008. Accordingly, the due date for the Brief on Appeal, having been extended, is September 2, 2008.

The fee required under 37 CFR §1.17(c) for the appeal should be charged to Deposit Account No. 13-3723.

Appellants request the opportunity for a personal appearance before the Board of Appeals to argue the issues of this appeal. The fee for the personal appearance will be timely paid upon receipt of the Examiner's Answer.

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REAL PARTY IN INTEREST

The real party in interest is Medtronic, Inc., 710 Medtronic Parkway, Minneapolis, Minnesota 55432-5604, as evidenced by the Assignment recorded on August 19, 2004 at Reel 015073, Frame 0502.

RELATED APPEALS AND INTERFERENCES

This application is a divisional of U.S. Patent Application Serial No. 10/278,769, filed October 22, 2002 which has been previously appealed to the Board of Patent Appeals and Interferences on by a Notice of Appeal filed on May 25, 2005. That appeal resulted in a decision by the Board of Patent Appeals and Interferences on December 29, 2006 reversing the Examiner. After subsequent Office Action, that application is currently under appeal to the Board of Patent Appeals and Interferences under a Notice of Appeal filed on April 2, 2008.

Appellant, Appellant's legal representative and the assignee are not aware of any other appeals or interference proceedings before the U.S. Patent and Trademark Office that will directly affect, be directly affected by, or have a bearing on the Board's decision in this appeal.

STATUS OF CLAIMS

Claims 1 – 13 are pending in this application.

Claims 1 – 7 and 9 – 13 have been rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Application Publication No. 2001/003370083 ("Hartlaub et al '083").

Claims 1 – 13 have been rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,731,051 ("Fischell '051").

Claims 1 – 10 and 12 – 13 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,069,668 ("Boydman '668") in view of U.S. Patent No. 4,731,051 ("Fischell '051").

Claims 1 – 13 are currently being appealed.

STATUS OF AMENDMENTS

All amendments have been entered. No amendments are pending.

SUMMARY OF CLAIMED SUBJECT MATTER

Drug infusion systems that deliver a therapeutic substance to a patient or patient tissue are well known in the art. Such drug infusion systems may be programmable by a medical professional by way of a programmer. Medical professionals and other users of drug infusion systems have previously been provided with various means for adjusting characteristics of when and how much of the therapeutic substance a drug infusion system will deliver. In various examples, the therapeutic substance may delivered steadily over time at a basal rate, or separate doses may be delivered at particular times, either in the form of a bolus dose or at a particular rate over a particular time interval.

In certain applications of programmable drug infusion systems, however, it may be beneficial to utilize both a programmable steady basal rate of drug delivery, as well as programmable interval deliveries in addition to the basal rate in order to automatically provide greater amounts of therapy to the patient at particular times than would be provided by the basal rate alone. For instance, a patient who requires a certain amount of therapeutic substance during the day may require increased amounts at night. Thus, a medical professional may program a basal rate of delivery, and then program interval rates on top of the basal rate over time intervals during evening and night hours. See Figure 3 of the application reproduced below by way of example. The cross-hatched area 120 represents the basal delivery rate. The portion of bar 110 which extends above basal rate area 120 represents the interval rate for one time slot. Similarly, the portion of bars 112, 116 and 118 which extend above basal rate area 120 represents the interval rate for additional time slots. No interval rate is specified for the time slots where no portion of bar 114 extends above the base rate 120.

Such an arrangement carries with it the convenience for a medical professional of not having to individually program interval rates over an entire 24 hour period, for instance, but rather allows the medical professional to set a single base rate, and then modify therapy delivery only during time intervals where a different rate of delivery may be needed.

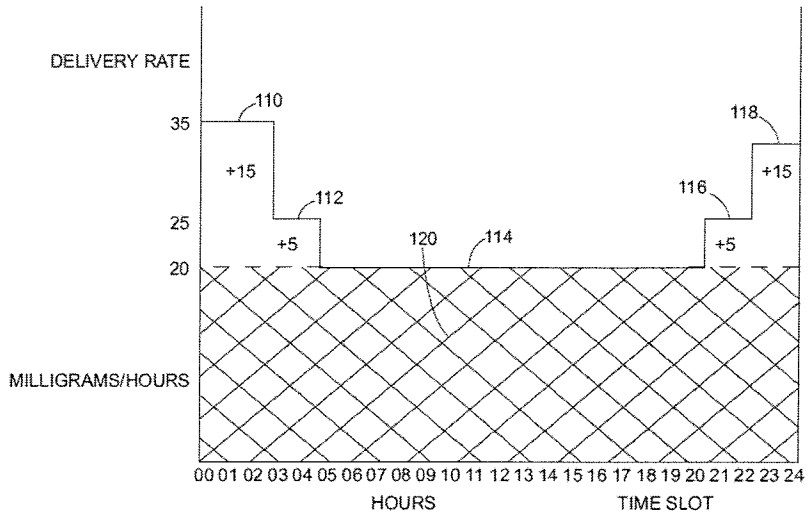

Fig. 3

However, some therapeutic substances that are used in drug infusion systems, which may be beneficial to the patient in limited amounts, may prove hazardous to the well-being of the patient if delivered in excessive amounts over limited timeframes. Such therapeutic substances are commonly accompanied by instructions for use that limit their total dose over a 24 hour period to a particular maximum allowable dose. Alternate timeframes for maximum doses are also known, such as one week. In any event, when programming a drug infusion system, a medical professional may, whether deliberately or accidentally, program the drug infusion system such that the interval rates combined with the basal rate result in a total dose that exceeds the maximum dose.

The present invention provides a method having both the convenience of allowing a medical professional to program a drug infusion system using both a basal rate and interval rates, while also preventing the total dose, created by the combination of the basal and interval rates, from exceeding the maximum dose. Where the medical professional programs the drug infusion system to deliver the therapeutic substance such that the total dose exceeds the maximum dose, the method adjusting the basal rate such that the total dose no longer exceeds the maximum dose. Alternatively, the medical professional may simply set a total dose and one or more interval rates, and the controller may set the basal rate so that the total dose is achieved.

There are two independent claims under consideration, namely claim 1 and claim 13.

Claim 1

Claim 1 recites a method of delivering a fluid medication from an implanted device to a patient under direction of a medical professional (paragraph [26], line 2 – paragraph [29], line 6). The implanted device is manually programmed with a maximum dose, a basal rate and a plurality of interval rates over a specified period of time, each individual one of the plurality of interval rates corresponding to an individual one of a plurality of time slots during the specified period of time (paragraph [29], lines 1 – 3; paragraph [38], lines 1 – 7). The system determines a total dose over the specified period of time based on the basal rate and the interval rates (paragraph [46], lines 1 – 6). The system adjusts the basal rate so that the total dose does not exceed the maximum dose (paragraph [46], lines 6 – 8). The fluid medication is delivered in accordance with the basal rate as adjusted and the plurality of interval rates (paragraph [47], lines 1 – 9).

Thus, claim 1 establishes a particular specified period of time (line 5), to which specified period of time other claim elements of refer. Thus, the basal rate is a particular base rate during the specified period of time, while the interval rates are in addition to the basal rate during a plurality of intervals during the specified period of time. Based on the programmed basal and interval rates, the system determines the total dose (i.e., the total amount of therapy that will be delivered) during the specified period of time, and compares that against the maximum dose for the specified period of time. If the determined total dose exceeds the maximum dose, then the basal rate for the specified period of time is reduced so that the total dose does not exceed the maximum dose. Thus, the elements of claim 1 tie together around the concept of the two different rates being delivered over the specified period of time, and ensuring that, over the specified period of time, a maximum amount of therapy delivery is not exceeded.

An advantage of the method of allowing a medical professional to set a basal rate and a plurality of interval rates, determining a total dose over the specified period of time and adusting the basal so that the total dose does not exceed a maximum dose is that the medical professional may easily set a rate of therapy delivery that applies generally, as well as interval rates that apply over particular intervals, potentially easing the programming process. The method prevents the medical professional from programming too much therapy delivery over a specified time period by preventing the total dose from being greater than the maximum dose. By lowering the basal

rate if the total dose exceeds the maximum dose, the method still allows the therapy to be concentrated during the intervals where greater therapy is needed while at the same time preventing excessive therapy delivery.

No "means plus function" elements are claimed.

Claim 13

Claim 13 recites a method of delivering a fluid medication from an implanted device to a patient under direction of a medical professional, the device being part of a system (paragraph [26], line 2 – paragraph [29], line 6). The implanted device is manually programmed with a basal rate and a plurality of interval rates over a specified period of time, each individual one of the plurality of interval rates corresponding to an individual one of a plurality of time slots during the specified period of time (paragraph [38], lines 1 – 7). The system determines a total dose over the specified period of time based on the basal rate and the interval rates (paragraph [46], lines 1 – 6). At least one of the interval rates is adjusted (paragraph [51], lines 2 – 3). The system adjusts the basal rate in accordance with the adjustment to the interval rate (paragraph [51], lines 3 – 6). The fluid medication is delivered in accordance with the basal rate as adjusted and the plurality of interval rates (paragraph [47], lines 1 – 9).

Thus, claim 13 establishes a particular specified period of time (line 5), to which specified period of time the other claim elements refer. Thus, the basal rate is a particular base rate during the specified period of time, while the interval rates are in addition to the basal rate during a plurality of intervals during the specified period of time. A total dose over the specified period of time is determined based on the basal and interval rates. When at least one of the interval rates is manually adjusted, the basal rate is adjusted in accordance with the adjustment to the interval rate. Thus, the elements of claim 1 tie together around the concept of initially programming the system with a total dose that is delivered over the specified period of time, and then, with subsequent adjustments to the interval rates, adjusting the basal rate accordingly to maintain at least some continuity with the total dose as initially programmed.

An advantage of the method of having a system that allows a medical professional to set a total dose to be delivered over a time period, as well as various interval rates during which the therapy delivery is to be relatively greater than at other times, and the method will automatically

set a basal rate to accomplish the total dose in view of the interval rates. Such an arrangement may also allow a medical professional to "lock-in" a certain total dose by automatically adjusting the basal rate in the event of changes to an interval rate.

No "means plus function" elements are claimed.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1 – 7 and 9 – 13 stand rejected under 35 USC § 102(e) as being anticipated by U.S. Patent Application No. 2001/0037083 ("Hartlaub et al '083").

Claims 1 – 13 stand rejected under 35 USC § 102(b) as being anticipated by U.S. Patent No. 4,731,051 ("Fischell '051").

Claims 1 – 10 and 12 – 13 stand rejected under 35 USC § 103(a) as being obvious over U.S. Patent No. 5,059,668 ("Boydman '668") in view of U.S. Patent No. 4,731,051 ("Fischell '051").

GROUPING OF CLAIMS

The claims are grouped as follows:

Group I: Claims 1 – 12.

Claim 1 is independent. Claims 2 – 12 depend from claim 1.

Group II: Claim 13 .

Claim 13 is independent. No claims depend from claim 13.

ARGUMENTS OF APPELLANTS

Rejections under 35 U.S.C. § 102(b)

U.S. Patent Application No. 2001,0037083, Hartlaub et al

Claims 1 – 7 and 9 – 13 stand rejected under 35 USC § 102(e) as being anticipated by U.S. Patent Application No. 2001/0037083 ("Hartlaub et al '083"). These grounds of rejection are currently being appealed.

Group I, Claims 1 – 7 and 9 – 12, over Hartlaub et al '083

Hartlaub et al '083 discloses an implantable drug infusion pump that allows a patient to self-administer additional bolus doses (Abstract). The implantable medical device will prevent the patient from administering too many bolus doses (paragraph [0030]). In addition to bolus doses, the implantable drug infusion pump also delivers therapy at a basal rate, of which the medical professional may program two or more, and which the patient may then switch among "that would be acceptable in reaching the daily dosages" (paragraph [0037]). Where too little medication is being delivered over a particular time period "the therapy program may prompt the patient … to use the patient controller to either activate a bolus dose of medication or to use the next highest base rate" (paragraph [0040]). Alternatively, when it appears that too much medication will be delivered, "the patient would be prompted by the notification mechanism to use the patient controller select a higher base rate in an attempt to reduce the amount of future bolus activation requests" (paragraph [0041]). Alternatively, "if the patient is nearing the maximum daily dose then the therapy program could deny further activation requests, activate the smallest programmed dose when an activation request is made by the patient or prompt the patient to select the next lowest base rate" (paragraph [0042]). Thus, Hartlaub et al '083 discloses working to prevent the delivery of drugs either above or below a certain range by prompting or inhibiting additional bolus doses, and by prompting the user to change the basal rate to a different setting.

However, Hartlaub et al '083 does not show, disclose or suggest manually programming a maximum dose, a basal rate and a plurality of interval rates, individual ones of which correspond to individual ones of a plurality of time slots. Hartlaub et al '083 instead discloses only patient initiated bolus doses. Nor does Hartlaub et al '083 show, disclose or suggest that the

system determines a total dose over a specified period of time based on the basal rate and a plurality of interval rates. Hartlaub et al '083 discloses only a post-hoc determination of how much therapy has been delivered, not determining based on pre-programmed rates how much therapy will be delivered. Further, Hartlaub et al '083 does not show, disclose or suggest the system adjusting the basal rate so that the total dose does not exceed the maximum dose. Rather, Hartlaub et al '083 may disable the ability of the patient to self-administer bolus doses, or it may prompt the user to set the basal rate to the next lowest setting in the event that the total amount of therapy over a time period exceeds a maximum value.

The system in Hartlaub et al '083 is fundamentally different from the method required by claim 1. Claim 1 recites manually programming a maximum dose, a basal rate and an interval rate, and that the system determines a total dose based on the basal rate and the interval rate and adjusts the basal rate so that the total dose does not exceed the maximum dose. The difference between claim 1 and the disclosure of Hartlaub et al '083 is fundamental. Because Hartlaub et al '083 only discloses monitoring the amount of therapy that has been delivered, there is no prospective ability of Hartlaub et al '083 to anticipate overdose situations and mitigate the impact of overdosing by spreading the reduction in therapy delivery over an extended period of time. Rather, Hartlaub et al '083 waits for overdosing to nearly occur, then prompts the patient to reduce therapy delivery at the last moment, increasing the impact on the patient relative to the impact of claim 1 by back-loading all of the reduction in therapy to the time period after the maximum has nearly been reached. Further, by inhibiting bolus doses Hartlaub et al '083 may be preventing the patient from receiving extra therapy at times when the patient may need extra therapy, even when it is known in advance of that time that the patient will need extra therapy. The subject matter of claim 1, which allows for interval rates to be programmed prospectively and reductions in the basal rate based on those interval rates if the total dose will exceed a maximum, allows for a medical professional to ensure that extra therapy will be delivered at important times.

Further, Hartlaub et al '083 does not show, disclose or suggest setting an interval rate in at least one of a plurality of time slots, thereby limiting the ability of a medical professional to customize therapy delivery in advance of therapy delivery. Further, Hartlaub et al '083 does not show, disclose or suggest the system determining a total dose based on the basal rate and the

interval rate and adjusting the basal rate so that the total dose does not exceed a maximum dose. Rather, Hartlaub et al '083 may restrict patient boluses or prompt the patient to lower the basal rate to the next lowest setting, which may cause discomfort to a patient who may need extra therapy at particular times of the day. As such, Hartlaub et al '083 does not show, disclose or suggest the system adjusting the basal rate so that a total dose does not exceed a maximum dose.

Hartlaub et al '083 does not show, disclose or suggest all of the elements of claim 1. Thus, claim 1 is not anticipated under 35 USC § 102(e) over Hartlaub et al '083.

Summary

In particular with respect to independent claim 1, Hartlaub et al '083 does not show, disclose or suggest manually programming a maximum dose, a basal rate and a plurality of interval rates over a specified period of time, each individual one of the interval rates corresponding to an individual one of a plurality of time slots. Nor does Hartlaub et al '083 show, disclose or suggest the system determining a total dose based on the basal rate and the interval rates, nor the system adjusting the basal rate so that the total dose does not exceed the maximum dose.

For at least these clear and explicit recitals in claim 1, the rejection of claim 1 under 35 USC § 102(e) as being anticipated by U.S. Patent Application No. 2001/0037083, Hartlaub et al, should be reversed.

Further, for purposes of this appeal claims 2 – 7 and 9 – 12 are grouped together with claim 1. Claims 2 – 7 and 9 – 12 depend from claim 1, and as such incorporate all of the subject matter of claim 1. Claims 2 – 7 and 9 – 12 further recite additional patentable subject matter. The rejections of claims 2 – 7 and 9 – 12 under 35 USC § 102(e) as being anticipated by U.S. Patent Application No. 2001/0037083, Hartlaub et al, should be reversed for the same reasons provided with respect to claim 1.

Group II, Claim 13, over Hartlaub et al '083

The discussion of Hartlaub et al '083 with respect to Group I is hereby incorporated in its entirety. In addition, Hartlaub et al '083 does not show, disclose or suggest the system adjusting a basal rate in accordance with a manual adjusting of at least one of the plurality of interval rates.

In fact, as noted above, Hartlaub et al '083 does not show, disclose or suggest an interval rate at all.

The system in Hartlaub et al '083 is fundamentally different from the method required by claim 13. Claim 13 recites manually programming a basal rate and a plurality of interval rates, the system determining a total dose based on the basal rate and the interval rate, manually adjusting at least one of the plurality of interval rates, and the system adjusting the basal rate in accordance with the plurality of interval rates as adjusted. The difference between claim 13 and the disclosure of Hartlaub et al '083 is fundamental. Hartlaub et al '083 discloses only prompting the patient to reduce a basal rate when the total delivered therapy approaches a maximum allowable amount, or inhibiting the patient from delivering additional boluses of therapy. As noted, Hartlaub et al '083 does not show, disclose or suggest an interval rate, and thus would not be capable of adjusting a basal rate based on an adjustment to an interval rate.

Hartlaub et al '083 does not show, disclose or suggest all of the elements of claim 13. Thus, claim 13 is not anticipated under 35 USC § 102(e) over Hartlaub et al '083.

Summary

In particular with respect to independent claim 13, Hartlaub et al '083 does not show, disclose or suggest manually programming a basal rate and a plurality of interval rates over a specified period of time, each individual one of the interval rates corresponding to an individual one of a plurality of time slots. Nor does Hartlaub et al '083 show, disclose or suggest the system determining a total dose based on the basal rate and the interval rates, nor manually adjusting at least one of the interval rates and the system adjusting the basal rate in accordance with adjustment to the interval rates.

For at least these clear and explicit recitals in claim 13, the rejection of claim 13 under 35 USC § 102(e) as being anticipated by U.S. Patent Application No. 2001/0037083, Hartlaub et al, should be reversed.

U.S. Patent No. 4,731,051, Fischell

Claims 1 – 13 stand rejected under 35 USC § 102(b) as being anticipated by U.S. Patent No. 4,731,051 ("Fischell '051"). These grounds of rejection are currently being appealed.

Group I, Claims 1 – 12, over Fischell '051

Fischell '051 discloses an implantable programmable infusion pump which records system utilization and performance data which enables the physician to determine the effectiveness of the patient's self-medication and evaluate pump performance. The controller records the number of pump actuations, the number of times a particular selection code was used to assign a supplemental prescription schedule or request half or full basal delivery or inhibit pump actuation or countermand current directives, and the number of unverifiable or inappropriate selection codes received by the controller (column 3, lines 44 – 56). Fischell '051 provides 3-hour and 24-hour integral running rate limiting software means. A running integral dosage limit means that enables the controller to suspend pump actuation when the dosage in a prescribed time window exceeds a limit. If the patient requests a pump activation which would result in medication exceeding the dosage limit in that respective time period, the pump is not actuated and the medication is not delivered.

Fischell '051 also provides an integrating rate limiter. An up/down counter is utilized. The counter stores M counts and a clock generates N counts/hour. Pump priming will be prohibited if M+N pulse are delivered the first hour, and if N pulses are delivered per hour thereafter. Again, this limiting mechanism stops the delivery of medication if the predetermined usage rate is exceeded.

The system in Fischell '051 is fundamentally different from the method claimed in claim 1. Claim 1 recites manually programming a maximum dose, a basal rate and an interval rate, and the system determining a total dose based on the basal rate and the interval rate and adjust the basal rate so that the total dose does not exceed the maximum dose. Fischell '051 does not show, disclose or suggest setting a plurality of interval rates in addition to a basal rate, and then determining a total dose based on the basal rate and the interval rates. Fischell '051 does not perform any action remotely resembling adjusting the basal rate based on a comparison of the total dose with the maximum dose. The system described in Fischell '051 will only prevent the pump from delivering additional medication should a maximum dosage be exceeded. Thus, Fischell '051 does not show, disclose or suggest an ability to prospectively anticipate a potential overdose of therapy, instead waiting until an overdose is about to occur before prompting an adjustment to therapy delivery, thus back-loading the reduction in therapy delivery rather than

evenly distributing the reduction and potentially preventing the patient from receiving increased doses when increased doses are most needed.

Fischell '051 does not show, disclose or suggest all of the elements of claim 1. Thus, claim 1 is not anticipated under 35 USC § 102(b) by Fischell '051.

Summary

In particular with respect to independent claim 1, Fischell '051 does not show, disclose or suggest manually programming a maximum dose, a basal rate and a plurality of interval rates over a specified period of time, each individual one of the interval rates corresponding to an individual one of a plurality of time slots. Nor does Fischell '051 show, disclose or suggest the system determining a total dose based on the basal rate and the interval rates, nor the system adjusting the basal rate so that the total dose does not exceed the maximum dose.

For at least these clear and explicit recitals in claim 1, the rejection of claim 1 under 35 USC § 102(b) as being anticipated by U.S. Patent No. 4,731,051, Fischell, should be reversed.

Further, for purposes of this appeal claims 2 – 12 are grouped together with claim 1. Claims 2 – 12 depend from claim 1, and as such incorporate all of the subject matter of claim 1. Claims 2 – 12 further recite additional patentable subject matter. The rejections of claims 2 – 12 under 35 USC § 102(b) as being anticipated by U.S. Patent No. 4,731,051, Fischell, should be reversed for the same reasons provided with respect to claim 1.

Group II, Claim 13, over Fischell '051

The discussion of Fischell '051 with respect to Group I is hereby incorporated in its entirety. In addition, Fischell '051 does not show, disclose or suggest manually adjusting at least one of the plurality of interval rates and the system adjusting the basal rate in accordance with the adjusted interval rates and delivering therapy based on the adjusted basal rate and interval rates. As noted above, Fischell '051 does not even show, disclose or suggest interval rates, and as such cannot show, disclose or suggest adjusting a basal rate based on adjustments to interval rates.

The system in Fischell '051 is fundamentally different from the method required by claim 13. Claim 13 recites manually programming a basal rate and a plurality of interval rates, the system determining a total dose based on the basal rate and the interval rate, manually adjusting

at least one of the plurality of interval rates, and the system adjusting the basal rate in accordance with the plurality of interval rates as adjusted. The difference between claim 13 and the disclosure of Fischell '051 is fundamental. Fischell '051 discloses only prompting the patient to reduce a basal rate when the total delivered therapy approaches a maximum allowable amount, or inhibiting the patient from delivering additional boluses of therapy. As noted, Fischell '051 does not show, disclose or suggest an interval rate, and thus would not be capable of adjusting a basal rate based on an adjustment to an interval rate. The system described in Fischell '051 will only prevent the pump from delivering additional medication should a maximum dosage be exceeded. Thus, Fischell '051 does not show, disclose or suggest an ability to automatically, prospectively compensate for an adjustment to at least one interval rate by adjusting the basal rate.

Fischell '051 does not show, disclose or suggest all of the elements of claim 13. Thus, claim 13 is not anticipated under 35 USC § 102(b) by Fischell '051.

Summary

In particular with respect to independent claim 13, Fischell '051 does not show, disclose or suggest manually programming a basal rate and a plurality of interval rates over a specified period of time, each individual one of the interval rates corresponding to an individual one of a plurality of time slots. Nor does Fischell '051 show, disclose or suggest the system determining a total dose based on the basal rate and the interval rates over a period of time, nor manually adjusting at least one of the interval rate and the system adjusting the basal rate over that period of time based on the adjustment to the interval rates.

For at least these clear and explicit recitals in claim 13, the rejection of claim 1 under 35 USC § 102(b) as being anticipated by U.S. Patent No. 4,731,051, Fischell, should be reversed.

Rejections under 35 U.S.C. § 103(a)

Claims 1 – 10 and 12 – 13 stand rejected under 35 USC § 103(a) as being obvious over U.S. Patent No. 5,059,668 ("Boydman '668") in view of U.S. Patent No. 4,731,051 ("Fischell '051").

Group I: Claims 1 – 10 and 12

The argument for the rejection of Group I under 35 U.S.C. § 102(b) is hereby incorporated in its entirety. As discussed above, Fischell '051 does not show, disclose or suggest manually programming a maximum dose, a basal rate and a plurality of interval rates over a specified period of time, each individual one of the interval rates corresponding to an individual one of a plurality of time slots. Nor does Fischell '051 show, disclose or suggest the system determining a total dose based on the basal rate and the interval rates, nor the system adjusting the basal rate so that the total dose does not exceed the maximum dose

Boydman '668 discloses a patient controlled analgesia system. The system may be pre-programmed by a physician to initially deliver a bolus dose (column 9, lines 44 – 46). After delivery of the bolus dose, a pre-programmed a "current rate" is set based on a "starting infusion rate" based on an amount of delivery at a "continuous infusion" rate commences delivery to the patient (column 9, lines 54 – 56). In addition, the patient may order "demand" doses based on patient need (column 9, lines 10, lines 2 – 4). The medical professional may further establish an "expectation" of patient demands into the system (column 10, lines 4 – 9). Based on that expectation, to the extent that the patient does not self-administer demand doses in the amount of the expectation, a rate adjustment factor may be applied to increase the current rate for a one-hour interval (column 10, lines 10 – 19). However, to the extent that the adjustment of the current rate would exceed a preset limit, the adjustment would not occur (column 10, lines 20 – 22). Thus, Boydman '668 provides for a bolus dose followed by an initialized current rate and demand doses. The current rate may be adjusted based on the number of demand doses that are self-administered by the patient relative to an expected number of demand doses, but the current rate may not stray outside of pre-set limits.

Thus, the system of Boydman '668 is fundamentally different from the method claimed in claim 1. Claim 1 recites manually programming a maximum dose, a basal rate and an interval rate, and the system determining a total dose of a specified period of time based on the basal rate and the interval rate and adjust the basal rate over that same specified period of time so that the total dose does not exceed the maximum dose. Boydman '668 does not show, disclose or suggest setting a plurality of interval rates in addition to a basal rate, and then determining a total dose over the specified period of time based on the basal rate and the interval rates. Boydman '668 does not perform any action remotely resembling adjusting the basal rate based on a

comparison of the determined total dose with the maximum dose. The system of Boydman '668 only adjusts the current rate to compensate for patient administered demand doses relative to a pre-programmed expectation, with the adjustment not taking the current rate outside of allowed bounds. Thus, Boydman '668 does not show, disclose or suggest an ability to prospectively anticipate a potential overdose of therapy, instead waiting until an overdose is about to occur before adjusting the current rate. Nor does Boydman '668 show, disclose or suggest any ability to pre-program an interval rate.

Neither Fischell '051 nor Boydman '668 show, disclose or suggest all of the elements of claim 1, either alone or in combination. Thus, claim 1 is not obvious under 35 USC § 103(a) over Boydman '668 in view of Fischell '051.

Claims 2 – 10 and 12 depend from claim 1, and as such incorporate all of the subject matter of claim 1. Claims 2 – 10 and 12 further recites additional patentable subject matter. Because claim 1 is not obvious over Fischell '051 in view of Boydman '668, and because claims 2 – 10 and 12 recite additional patentable subject matter, claims 2 – 10 and 12 are not obvious under 35 USC § 103(a) over Boydman '668 in view of Fischell '051.

KSR v. Teleflex Examination Guidelines

The Examiner did not rely on the Examination Guidelines for Determining Obviousness in View of *KSR v. Teleflex*. However, even if the Examiner had done so, the *KSR* rationales to support rejections under 35 USC § 103(a) have not been met.

Combining Prior Art Elements According to Known Methods To Yield Predictable Results. The requirements of claim 1 are not a combination of prior art elements according to known methods to yield predictable results. The Examiner has not cited prior art to show a basal rate and an interval rate with a **controller** determining a total dose and adjusting the basal rate based on a maximum dose.

Simple Substitution of One Known Element for Another To Obtain Predictable Results. The requirements of claim 1 are not a simple substitution of one known element for another to obtain predictable results. There is no combination of elements in the cited art that incorporates all of the limitations of claim 1 with one difference that is shown in other cited art. No cited art shows, discloses or suggests determining a total dose based on two different rates, and no cited

art shows, discloses or suggests adjusting a rate based on a comparison of a determined total dose with a maximum dose.

Use of Known Technique To Improve Similar Devices in the Same Way. Assuming *arguendo* that the requirements of claim 1 constitute an improvement over a base device, the Examiner has made no finding that there is a "comparable" device in the art that was improved in the same way.

Applying a Known Technique to a Known Device Ready for Improvement To Yield Predictable Results. The requirements of claim 1 does not apply a known technique to a known device ready for improvement to yield predictable results. The Examiner has not shown that claim 1 describes a known device that was ready for improvement, what the known device might be, and that the results of using a basal rate and an interval rate to determine a total dose which may then be compared against a maximum dose and the basal rate adjusted based on that comparison would be predictable.

'Obvious To Try' – Choosing From a Finite Number of Identified, Predictable Solutions, With a Reasonable Expectation of Success. The requirements of claim 1 were not obvious to try. The Examiner has not shown that there was a recognized problem or need in the art, nor did the Examiner make a finding that there was a finite number of identified, predictable solutions to the recognized need or problem.

Known Work in One Field of Endeavor May Prompt Variations of it for Use in either the Same Field or a Different One Based on Design Incentives or Other Market Forces if The Variations Would Have Been Predictable to One of Ordinary Skill in the Art. The Examiner has made no findings that the scope or content of the prior art included a similar or analogous device and that there were design incentives or market forces which would have prompted adaptation of the known device, and that the differences between the requirements of claim 1 and the prior art were encompassed in known variations or in a principle known in the prior art.

Some Teaching, Suggestion or Motivation in the Prior Art That Would Have Led One of Ordinary Skill To Modify the Prior Art Reference or To Combine Prior Art Reference Teachings To Arrive at the Claimed Invention. There is no teaching, suggestion or motivation in Fischell '051 or Boydman '668 to utilize the subject matter of claim 1.

Summary

In particular, with respect to independent claim 1, neither Fischell '051 nor Boydman '668, alone or in combination, show, disclose or suggest a basal rate and an interval rate over a specified period of time, with those rates determining a total dose, and adjusting the basal rate over that specified period of time based on a comparison of the total dose with a maximum dose.

For at least these clear and explicit recitals in claim 1, claim 1 is not obvious under 35 USC § 103(a) over U.S. Patent No. 5,069,668, Boydman in view of U.S. Patent No. 4,731,051, Fischell.

Further, for purposes of this appeal, claims 2 – 10 and 12 are grouped together with and depend from independent claim 1. As such, claims 2 – 10 and 12 incorporate all of the subject matter of claim 1, and claim additional patentable subject matter. The rejections of claims 2 – 10 and 12 under 35 USC § 103(a) as being obvious over U.S. Patent No. 5,069,668, Boydman, in view of U.S. Patent No. 4,731,051, Fischell, should be reversed for the same reasons provided with respect to claim 1.

Group II: Claim 13

The argument for the rejection of Group II under 35 U.S.C. § 102(b) is hereby incorporated in its entirety. As discussed above, Fischell '051 does not show, disclose or suggest manually programming a maximum dose, a basal rate and a plurality of interval rates over a specified period of time, each individual one of the interval rates corresponding to an individual one of a plurality of time slots. Further, Fischell '051 does not show, disclose or suggest manually adjusting at least one of the plurality of interval rates and the system adjusting the basal rate in accordance with the adjusted interval rates and delivering therapy based on the adjusted basal rate and interval rates.

Boydman '668 discloses a patient controlled analgesia system. The system may be pre-programmed by a physician to initially deliver a bolus dose (column 9, lines 44 – 46). After delivery of the bolus dose, a pre-programmed a "current rate" is set based on a "starting infusion rate" based on an amount of delivery at a "continuous infusion" rate commences delivery to the patient (column 9, lines 54 – 56). In addition, the patient may order "demand" doses based on patient need (column 9, lines 10, lines 2 – 4). The medical professional may further establish an

"expectation" of patient demands into the system (column 10, lines 4 – 9). Based on that expectation, to the extent that the patient does not self-administer demand doses in the amount of the expectation, a rate adjustment factor may be applied to increase the current rate for a one-hour interval (column 10, lines 10 – 19). However, to the extent that the adjustment of the current rate would exceed a preset limit, the adjustment would not occur (column 10, lines 20 – 22). Thus, Boydman '668 provides for a bolus dose followed by an initialized current rate and demand doses. The current rate may be adjusted based on the number of demand doses that are self-administered by the patient relative to an expected number of demand doses, but the current rate may not stray outside of pre-set limits.

Thus, the system of Boydman '668 is fundamentally different from the method claimed in claim 13. Claim 13 recites manually programming a basal rate and a plurality of interval rates over a period of time, the system determining a total dose based on the basal rate and the interval rate over that period of time, manually adjusting at least one of the plurality of interval rates, and the system adjusting the basal rate in accordance with the plurality of interval rates as adjusted. The difference between claim 13 and the disclosure of Fischell '051 is fundamental. Boydman '668 does not show, disclose or suggest setting a plurality of interval rates in addition to a basal rate and a maximum dose, and then determining a total dose based on the basal rate and the interval rates. Boydman '668 does not adjust an interval rate, instead allowing for a demand doses and subsequently adjusting the current rate based on the administration of demand doses, or lack thereof. The system of Boydman '668 only adjusts the current rate to compensate for patient administered demand doses relative to a pre-programmed expectation, with the adjustment not taking the current rate outside of allowed bounds. Thus, Boydman '668 does not show, disclose or suggest an ability to prospectively anticipate a potential overdose of therapy, instead waiting until an overdose is about to occur before adjusting the current rate. Nor does Boydman '668 show, disclose or suggest any ability to pre-program an interval rate.

Neither Fischell '051 nor Boydman '668 show, disclose or suggest all of the elements of claim 13, either alone or in combination. Thus, claim 13 is not obvious under 35 USC § 103(a) over Boydman '668 in view of Fischell '051.

KSR v. Teleflex Examination Guidelines

The Examiner did not rely on the Examination Guidelines for Determining Obviousness in View of *KSR v. Teleflex*. However, even if the Examiner had done so, the *KSR* rationales to support rejections under 35 USC § 103(a) have not been met.

Combining Prior Art Elements According to Known Methods To Yield Predictable Results. The requirements of claim 13 are not a combination of prior art elements according to known methods to yield predictable results. The Examiner has not cited prior art to show a total dose and an interval rate with the system determining a basal rate based on the total dose and the interval rate.

Simple Substitution of One Known Element for Another To Obtain Predictable Results. The requirements of claim 13 are not a simple substitution of one known element for another to obtain predictable results. There is no combination of elements in the cited art that incorporates all of the limitations of claim 13 with one difference that is shown in other cited art. No cited art shows, discloses or suggests determining a basal rate based on an interval rate and a total dose.

Use of Known Technique To Improve Similar Devices in the Same Way. Assuming *arguendo* that the requirements of claim 13 constitute an improvement over a base device, the Examiner has made no finding that there is a "comparable" device in the art that was improved in the same way.

Applying a Known Technique to a Known Device Ready for Improvement To Yield Predictable Results. The requirements of claim 13 do not apply a known technique to a known device ready for improvement to yield predictable results. The Examiner has not shown that claim 13 describes a known device that was ready for improvement, what the known device might be, and that the results of using a total dose and an interval rate to determine a basal rate would be predictable.

'Obvious To Try' – Choosing From a Finite Number of Identified, Predictable Solutions, With a Reasonable Expectation of Success. The requirements of claim 13 were not obvious to try. The Examiner has not shown that there was a recognized problem or need in the art, nor did the Examiner make a finding that there was a finite number of identified, predictable solutions to the recognized need or problem.

Known Work in One Field of Endeavor May Prompt Variations of it for Use in either the Same Field or a Different One Based on Design Incentives or Other Market Forces if The Variations Would Have Been Predictable to One of Ordinary Skill in the Art. The Examiner has made no findings that the scope or content of the prior art included a similar or analogous device and that there were design incentives or market forces which would have prompted adaptation of the known device, and that the differences between the requirements of claim 13 and the prior art were encompassed in known variations or in a principle known in the prior art.

Some Teaching, Suggestion or Motivation in the Prior Art That Would Have Led One of Ordinary Skill To Modify the Prior Art Reference or To Combine Prior Art Reference Teachings To Arrive at the Claimed Invention. There is no teaching, suggestion or motivation in Fischell '051 or Boydman '668 to utilize the subject matter of claim 13.

Summary

In particular, with respect to independent claim 13, neither Fischell '051 nor Boydman '668, alone or in combination, show, disclose or suggest a basal rate and an interval rate over a period of time, adjusting the interval rate, and the system adjusting the basal rate over that period of time based on the adjustment to the interval rate.

For at least these clear and explicit recitals in claim 13, claim 13 is not obvious under 35 USC § 103(a) over U.S. Patent No. 5,069,668, Boydman, in view of U.S. Patent No. 4,731,051, Fischell.

Summary

In view of the arguments presented, the rejection of claims 1 – 7 and 9 – 13 under 35 USC § 102(e) as being anticipated by U.S. Patent Application No. 2001/0037083, Hartlaub et al, should be reversed. In view of the arguments presented, the rejection of claims 1 – 13 under 35 USC § 102(b) as being obvious over U.S. Patent No. 4,731,051, Fischell, should be reversed. In view of the arguments presented, the rejection of claims 1 – 10 and 12 – 13 under 35 USC § 103(a) as being obvious over U.S. Patent No. 5,069,668, Boydman, in view of U.S. Patent No. 4,731,051, Fischell, should be reversed.

Respectfully submitted,

Registration Number	Telephone Number
28,052	612-334-7405
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September 2, 2008	

By _____
William D. Bauer

APPENDIX

LISTING OF CLAIMS

1. (previously presented) A method of delivering a fluid medication from an implanted device to a patient under direction of a medical professional, said implanted device being part of a system, comprising the steps of:

manually programming said implanted device with a maximum dose, a basal rate and a plurality of interval rates over a specified period of time, each individual one of said interval rates corresponding to an individual one of a plurality of time slots during said specified period of time;

said system determining a total dose over said specified period of time based on said basal rate and said interval rates, each individual one of said interval rates corresponding to an individual one of said plurality of time slots;

said system adjusting said basal rate so that said total dose does not exceed said maximum dose; and

delivering said fluid medication in accordance with said basal rate as adjusted in said adjusting step and said plurality of interval rates specified in said programming step.

2. (original) A method of delivering a fluid medication as in claim 1 wherein said total dose equals said maximum dose.

3. (previously presented) A method of delivering a fluid medication as in claim 1 wherein said plurality of interval rates may be programmed individually for each of said plurality of time slots.

4. (original) A method of delivering a fluid medication as in claim 3 wherein at least two of said plurality of time slots are of unequal duration.

5. (original) A method of delivering a fluid medication as in claim 1 wherein said period of time is a day and wherein said total dose is a daily dose.

6. (original) A method of delivering a fluid medication as in claim 5 wherein at least two of said plurality of time slots are of equal duration.

7. (original) A method of delivering a fluid medication as in claim 1 wherein said control may be programmed separately for each day of a week.

8. (original) A method of delivering a fluid medication as in claim 7 wherein days of each of said week may be grouped together and programmed together.

9. (original) A method of delivering a fluid medication as in claim 1 wherein said controller provides a graphical display of said interval rate in each of said plurality of time slots.

10. (original) A method of delivering a fluid medication as in claim 9 wherein said controller provides said graphical display to said medical professional.

11. (original) A method of delivering a fluid medication as in claim 9 wherein said graphical display comprises a bar graph having a bar for each of said plurality of time slots and wherein in said bar has a length proportional to said basal rate and said interval rate.

12. (previously presented)A method as in claim 1 wherein said programming step occurs before a beginning of said specified period of time.

13. (previously presented) A method of delivering a fluid medication from an implanted device to a patient under direction of a medical professional, said implantable medical device being part of a system, comprising the steps of:

manually programming said implanted device with a basal rate and a plurality of interval rates over a specified period of time, each individual one of said interval rates corresponding to an individual one of a plurality of time slots during said specified period of time;

said system determining a total dose over said specified period of time based on said basal rate and said interval rate;

manually adjusting at least one of said plurality of interval rates;

said system adjusting said basal rate in accordance with said plurality of interval rates as adjusted in said manually adjusting step; and

delivering said fluid medication in accordance with said basal rate as adjusted in said adjusting step and said plurality of interval rates.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.